

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and following remarks, and also those arguments presented in the Appeal Brief filed June 19, 2006 and amended Appeal Brief filed October 25, 2006, which are incorporated by reference herein. The present amendment is filed with a Request for Continued Examination and is a submission under 37 C.F.R. § 1.114. This amendment is filed in response to the final Office Action dated October 3, 2005 and is provided further to the Notice of Appeal filed February 1, 2006 and the Appeal Brief filed June 19, 2006.

Prior to this amendment claims 36, 43, and 66-68 were pending and under consideration. By the present amendment, new claims 69 and 70 are added to more specifically recite certain embodiments of the presently claimed invention. Applicants submit that these claims do not include new matter and are supported by the specification and claims as originally filed. Specifically, the drug:lipid ranges of 0.2-0.5:1 and 0.3-0.5:1 (w/w) are supported by the description of the range of 0.1-0.5:1 in paragraph 33 of the application as filed, in light of the description of specific drug:lipid ratios of 0.2:1 and 0.3:1 provided in Figure 1. Applicants respectfully submit that numerical range limitations are considered adequately supported if they would be considered inherently supported by the discussion in the original disclosure. MPEP 2163.05. For example, in the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." Accordingly, a limitation to "between 35% and 60%" was considered supported and found to satisfy the written description requirement.

It should also be noted that the above amendments are made without prejudice to prosecution of any subject matter removed or modified by amendment in a related divisional, continuation or continuation-in-part application.

Rejection Under 35 U.S.C. § 103

Claims 36, 43, and 66-68 stand rejected under 35 U.S.C. § 103 as obvious over the combination of U.S. Patent No. 6,110,491 ("Kirpotin") and U.S. Patent No. 5,543,152 ("Webb").

Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection in light of the arguments submitted in the Appeal Brief filed June 19, 2006 and the Amended Appeal Brief filed October 25, 2006. Applicants note that the arguments presented in these briefs are identical. The only difference between the two briefs is that the Amended Appeal Brief also includes headings titled Evidence Appendix and Related Proceedings Appendix. Applicants hereby incorporate by reference herein the arguments presented in these Appeal Briefs in their entirety. Applicants request that the arguments and evidence presented in these briefs is made of record in the instant application, including the arguments based upon information described in U.S. Patent No. 5,741,516, which is related to Webb as a continuation-in-part application.

In addition, as further evidence supporting the patentability of the presently claimed liposomal vinorelbine formulations, Applicants submit herewith a Declaration of Dr. Thomas D. Madden, which describes the unexpected and surprising finding that liposomal vinorelbine formulations having a high vinorelbine:lipid ratio, *e.g.*, 0.1-0.5:1 (w/w) have enhanced drug retention as compared to those having lower drug:lipid ratios. As noted in Dr. Madden's declaration, this discovery contravenes the conventional understanding in the art at the time, which was that higher drug:lipid ratios result in more rapid drug release from liposomes. Accordingly, the presently claimed invention, drawn to liposomal vinorelbine formulations having a high drug:lipid ratio, possesses surprising and unexpected advantages, which would not have been evident to one of skill in the art at the time the instant application was filed. Furthermore, one of skill in the art, possessed with the understanding that higher drug:lipid ratios result in increased drug release, would not have been motivated to use the presently claimed high vinorelbine:lipid ratios, since slow drug release is generally considered a desired property in liposomal drug formulations.

In light of these remarks, including those incorporated by reference from the appeal briefs and the accompanying Declaration establishing the existence of unexpectedly superior pharmacokinetic properties of the claimed liposomal compositions, Applicants respectfully request that the Examiner reconsider and withdraw this basis of rejection.

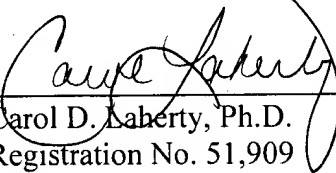
The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

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Applicants submit that all of the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Should any issues remain prior to allowance, the Examiner is requested to contact the undersigned attorney at (206) 622-4900.

Respectfully submitted,

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Enclosure:

Declaration of Thomas D. Madden, Ph.D.

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